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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,905	04/24/2000	TOHRU TANI	FJN-077	7282

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/423,905	TANI ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 10-25-04 has been entered into the record. Claims 2-5 and 8-10 are pending and under examination. Claims 1, 6-7 and 11-35 have been cancelled.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 2-5, 8-10, 13-16, 19-21 and 24-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants amendments to the claims or cancellation of the claims.

The rejection of claims 2-5, 8-10 and 34-35 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reducing sepsis-associated lethality in a cecum-punctured rate that develops sepsis, comprising administering an amount of isolated or purified tissue cytotoxic factor-II (TCF-II) effective to reduce sepsis associated lethality, wherein the TCF-II is administered prior to the cecum being punctured and the onset of sepsis, it does not reasonably provide enablement for methods for reducing the lethality in a mammal that develops sepsis by administering an amount of isolated or purified tissue cytotoxic factor-II (TCF-II) effective to reduce sepsis associated lethality, wherein the TCF-II is administered prior to the onset of sepsis is withdrawn in view of Applicants amendments to the claims or cancellation of the claims.

The rejection of claims 16, 24, 28, 30 and 35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention is withdrawn based on the cancellation of the claims.

The rejection of claims 13-16, 19-21, and 28-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn based on cancellation of the claims.

The rejection of claims 13-16, 19-21, 31 and 33 under 35 U.S.C. 102(b) as being anticipated by Masunaga et al (Canadian Patent Application 2100720, Open to public inspection 01/17/94) is withdrawn in view of cancellation of the claims.

Rejections Maintained

Claims 2-5 and 8-10 under 35 U.S.C. 102(b) as being anticipated by Masunaga et al (U.S. Patent No. 5,714,461, issued Feb 3, 1998) is maintained.

As to claims 2-5 and 8-10, the claims are now drawn to administering an amount of isolated or purified tissue cytotoxic factor-II (TCF-II) effective to reduce sepsis-associated lethality in a mammal with sepsis, wherein TCF-II is administered.

Masunaga et al teach treating disseminated intravascular coagulation (DIC) syndrome wherein the DIC is caused by the basal disease sepsis (see paragraph bridging columns 1-2). This passage is interpreted to indicate that patients with sepsis-associated DIC are to be treated. Further, treatment of disease accompanying decreases of platelets and thrombopoietin deficient infections such as sepsis are also specifically illustrated as indications of the invention of Masunaga et al (column 3, lines 55-67). Masunaga et al teach the administration of TCF-II by intravenous route in 10 mM phosphate buffer, pH 6.8-7.2, containing 0.01% Tween 80 and 0.25% human serum albumin and 0.15M sodium chloride (column 7, lines 1-5). Masunaga et al teach that the TCF-II may be administered by a variety of routes such as intravenous, intraarterial, intramuscular

and subcutaneous (column 3, lines 35-41). Further, Masunaga et al teach that the following diseases may be illustrated of indications of the present invention including ".. thrombopoietin deficient infections such as sepsis...(column 3, lines 55-67). Thus, Masunaga et al specifically teach treatment of septic patients having DIC or septic patients with thrombopoietin deficiency. The identical pharmaceutical agents are administered to mammals with sepsis-associated DIC. Therefore, the claimed function of "reducing sepsis-associated lethality" is an inherent function of the administration of TCF-II to septic patients having DIC or diseases accompanying thrompotoietin deficient infections such as sepsis as specifically taught by Masunaga et al.

Applicants argue that Masunaga et al does not apply because DIC can be caused by a variety of basal diseases and does not describe specifically recite reduction of septic-associated lethality. This is not persuasive, Masunaga et al specifically contemplates the administration of the identical reagent to septic patients having DIC. Therefore, administration of TCF-II to septic patients having DIC, or diseases such as sepsis specifically illustrated as indicated as the invention according to the teaching of Masunaga et al, in fact practices the claimed method and the outcome of reduction of lethality associated with administering the TCF-II to septic patients. The fact that all DIC patients do not have sepsis is irrelevant to the specific teaching that septic patients having DIC are treated according to Masunaga et al or the specific illustration of sepsis as an indication of the invention as specifically recited in Masunaga et al. While the prior art disclosure may be silent as to the "reducing sepsis-associated lethality" per se; ; the instant claims merely recite newly discovered results of "reducing sepsis-associated lethality" of a known method of treating the same or nearly the same patients (patients with sepsis-associated DIC; thrombopoietin deficient infection such as sepsis) with the TCF-II. The claim language is a statement of purpose and intended result and does result in a manipulative difference in the method steps of the claims. The recitation of "effective amounts" statement of the intended results of administering those amounts

does not change those amounts or otherwise limit the claim. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 00-1304 (CAFC 4/20/01). Therefore, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. On this record, it is reasonable to conclude that the art contemplates a septic patient having DIC or sepsis as an indication of the invention as being administered the same active agent by the same modes of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Applicants appear to further argue that the patent did not specifically administer the TCF-II to patients having sepsis *per se*. This is not persuasive, Masunaga et al contemplate administration of TCF-II to septic patients having DIC and sepsis is specifically contemplated as illustrated as indications of the invention of Masunaga et al. Septic patients having DIC is a subgenus of all septic patients and therefore anticipates the instant method. Further, the examiner does not concede that Masunaga et al does not teach treatment of sepsis or the administration of patients having sepsis. Masunaga et al specifically teach that infections such as sepsis are illustrated as an indication of the invention. As such, Masunaga specifically taught administration of TCF-II in sepsis. It is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. See In re Woodruff 16 USP2d 1934, 1936, (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. Additionally, in similar circumstances, the courts have held that the preamble was non-limiting because it merely recited the purpose of the process which is set forth in the body of the claim (In re Hirao 190 USPQ 15, 16-17, (CCPA 1976)). The express dosage amount are material claim limitations, the

statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim. The sole method step is administering. The method of the prior art teaches administering. The prior art teaches both the single step and the patient population (sepsis associated DIC or sepsis). The courts have held that the prior art to serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). *See Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). In the instant case, the art enables one skilled in the art to make TCF-II and administer the TCF-II to septic patients having DIC or sepsis according to Masunaga et al. The functional outcome of reducing sepsis-associated lethality is an inherent function arising from the method of the prior art. There is no requirement that the reference reduce to practice as apparently asserted by Applicants.

The rejection is maintained.

Status of Claims

Claims 2-5 and 8-10 stand rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 am - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645